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Inventors : Natesan & Gilman

For : Chimeric Transcription Factors

Art Group: 1632

TECH CENTER 1600/2900

Examiner: Shukla, Ram R.

Commissioner of Patents & Trademarks
Washington, DC 20231

May 22, 2002

Request for Three Month Extension & Response to Office Action

This is in Response to the Office Action mailed on 1/23/02, a response to which was originally due on 2/23/02. Applicants hereby request a three-month extension for responding and authorize the Commissioner to charge the fee for such extension to Deposit Account No. 01-2315. The new deadline is now 5/23/02, and this response should be considered timely filed.

Response to Restriction Requirement

Applicants thank the Examiner for reconsidering and restructuring the prior restriction—even though it led to more groups than before. We look forward to working with the Examiner on the substantive prosecution of our claims.

But first, applicants do take issue, respectfully, with a few aspects of the Office Action:

(1) The description of Group III is not completely correct. Group III is drawn to organisms and uses thereof, but also contains claims 54 and 55 which involve methods for *making* the organisms—rather than *using* them. Methods of making the organisms are covered in Group V. The “method of making” claims are thus split between Groups III and V. That split seems arbitrary. It will complicate the choice of related applications in which to prosecute “method of making” claims (query: will a subsequently drafted or amended “method of making” claim need to be prosecuted in an application bearing the Group III claims or bearing the Group V claims?). Applicants suggest that the description of Group III be amended, that claims 54 and 55 be moved from Group III into Group V or that claims 56 – 59 be moved from Group V into Group III.

(2) The claims to methods for stimulating transcription of a target gene by administering ligand to the organism are split between Groups III and V. Again, this is a split which seems arbitrary and will complicate the choice of related applications in which to prosecute method of use claims.

(3) Point #4 in the Office Action identifies the following as a key distinction between Group II and Group V: that the cells and methods of Group II involve cells (*in vitro*) whereas the subject matter of Group V relates to organisms. However, that distinction is not quite correct. The claims of Group II are generic to cells *in vitro* and cells within an organism. See e.g. claims 43 and 44. Furthermore, the conclusion that the inventions of Groups II, IV and V are unrelated is inconsistent with the

finding that Groups II and V are related (along with Group I; O.A. point #4) and that Groups II and IV are related (along with III; O.A. page 3, 1st new paragraph).

—Yes, it is difficult, if not impossible, to divide these claims in a non-arbitrary manner leading to a set of discrete companion cases permitting streamlined searching and examination. That difficulty results from the particularly close connection between all of the claims, as recognized by the Examiner in point #3, page 2, of the 1/23/02 Office Action. Because of that close connection, we suggest that the search will be the same or substantially the same no matter how the claims are segregated, and in fact, would be the same in the absence of restriction. Thus, search and consideration of the entire claimed subject matter would not be unduly burdensome despite technical distinctions between the various claims. In contrast we point again to the burden applicants will have to bear in connection with prosecuting multiple, intertwined applications.

In view of the foregoing, applicants traverse the restructured restriction requirement issued under the PTO's discretionary authority provided by 35 USC 121.

For the sake of a complete response, applicants provisionally elect Group II, with traverse, with the understanding that claims 1 – 38 will also be examined as stated in Point #3 in the last Office Action. However, given the recurrence in subsequent claims of key limitations from claims 1 - 38, applicants request, upon a finding of patentable subject matter, that the examiner consider expanding the examination to consider also any remaining non-elected claims together with the elected claims.

Response to Election of Species Requirement

The pending Office Action maintains the previous position that the following are patentably distinct species of the claimed invention: a transcription potentiation domain, a DNA binding domain, tetR repressor domain and a stabilization domain. However, those listed items, whether or not they are patentably distinct, are not species of the invention—they are an arbitrarily selected partial list of claim elements. The listed elements are a subset of the *components* of certain of the various species of the claimed invention. They are not species of the invention themselves and therefore can't be the subject of a requirement for an election of species.

Accordingly, because those items represent a partial list of elements of various embodiments of the invention and are *not* themselves species of the invention, the fact that each of those elements may have acquired a separate status in the art and may require a separate search is not relevant to restriction practice and does not make restriction or election of one of them necessary or proper under current PTO practice. Again, since they are not species of the invention they are not the things one can elect.

However, in order to provide a complete response, applicants provisionally elect, with traverse, the following species of the invention, and suggest that it be used simply to help focus the search:

The introduction into cells of a recombinant nucleic acid encoding a fusion protein containing a p65 domain (361 – 551) and a T2098L-mutant FRB domain (see Example IV on pages 69 – 70 of the specification).



Applicants thus respectfully traverse the restriction requirement and the election of species requirement, but do so with provisional elections in order that this response be deemed complete. However, in the event that the restriction or species election requirement is withdrawn or redrafted, applicants reserve the right to make different elections consistent with those changed circumstances.

We do appreciate the Examiner's time and thought spent at this early stage and look forward to working with the Examiner during the ensuing prosecution of this important case. If it might be helpful in answering any questions or otherwise advancing prosecution, applicants earnestly invite the Examiner to call their attorney at the number provided below.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: ~~Assistant~~ Commissioner for Patents Washington, D.C. 20231 on the date indicated below:

date: May 22, 2002

Sue Wilson
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